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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,000	03/13/2001	Geert Jannes	2752-33	1152

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HILL, MYRON G	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/787,000	JANNES ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,15,17,20,21,23-25,27-29,31,33 and 35-49* is/are pending in the application.

4a) Of the above claim(s) *37-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,15,20,21,23-25,27-29,31 and 33* is/are rejected.

7)☒ Claim(s) *17,35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

This action is in response to the amendment filed 5/8/06 and the petition decision. Claims 13, 15, 17, 20, 21, 23-25, 27-29, 31, 33, 35, and 36 are under consideration.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 13 March 2001 is enclosed with the one remaining item signed off on.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant is not required to write out each step when the step is clear from the preamble of the claim.

Rejections Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13, 15, 18, 20, 21, 23, 24, 29, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jannes *et al.* (US 6,025,132), Claas et al. (Journal of Virological Methods. 1992; 39 (1-2) 1-13, abstract only), Paton et al. (Journal of Clinical Microbiology. 1992; 30 (4): 901-904, abstract only), Kinchington et al. (Investigative Ophthalmology and Visual Science. 1994; 35 (12): 4126-34, abstract only), Saikku et al. (Clinical Microbiol and Infect. 1997; 3 (6): 599-606), Gilbert et al. (Journal of Clinical Microbiology. 1996; 34 (1): 140-143), Fluitt et al. (WO 95/13396. May, 1995), and Echevarria et al. (Journal of Clinical Microbiology. May, 1998; 36 (5): 1388-1391).

The some of the dependent claims have been amended to require detection with at least two probes.

Applicant argues that the examiner used nine references to allege that the the use of one primer pair and one probe are not obvious, the Saikku teach the future, not what the examiner states, that the prior art does not teach simulatanious amplification and or detection of multiple organisms at one time, and that it is common to the art cited by the examiner that only 1-3 organisms are amplified at one time.

Applicant's arguments have been fully considered and not found persuasive.

First, Applicant was looking for the literal printing of what the examiner paraphrased. The sentence following what applicant quotes as what the examiner paraphrased, NA based assays provide "a sensitive and specific diagnosis for these pathogens in 24 h." This is not an obvious to try but clearly an indication that the tests are "sensitive and specific".

Jannes *et al.* teach detection of 1 or more microorganisms and from claims 1 and 2 it is clear that Jannes *et al.* is not limited to 3 sequences. Each sequence can detect a different organism. Jannes *et al.* also teach that modification of primers/probes can be used to obtain the desired specificity and sensitivity (column 9, lines 5-10).

Echeverria *et al.* teach the simultaneous PCR amplification and probe detection of clinical samples to determine if the sample contains PIV-1, PIV-2, or PIV-3 using a primer mixture and amplifies the hemagglutininneuraminidase gene for PIV-1, see the materials and methods section. Also taught is that it is known in the art to design probes to function in multiplex assays (page 1388, column 2, last part paragraph).

It would have been obvious to one of ordinary skill in the art at the time of invention to have combined multiple primers/probes in one assay as needed to amplify and detect microorganisms because Jannes *et al.* teach modifying primers and detecting multiple microorganisms and Echeverria *et al.* teach it is within the ordinary skill in the art to design primers for multiplex assays.

One of ordinary skill in the art at the time the invention was made would have been motivated to simultaneously detect respiratory tract disease organisms and

viruses to more quickly determine the pathologic cause of the disease to administer the proper treatment as soon as possible because Saikku *et al.* teach that there are no symptoms that readily differentiate the pathogen causing the respiratory infection, see the last paragraph on page 600. Therefore, simultaneous detection of multiple organisms would eliminate improper diagnosis and treatment because specific identification of the pathogen(s) causing the infection would be known. One of ordinary skill in the art at the time the invention was made would have been further motivated to PCR amplify respiratory tract infections because the method is less time consuming than culturing swabs from the respiratory tract of an infected individual and because PCR is a more sensitive, specific and accurate detection technique. Gilbert *et al.* teach that the PCR method had over 94% sensitivity for detecting the different viruses. One of ordinary skill in the art at the time the invention was made would have combined the specific primers and probes to amplify the instant regions taught by Claas *et al.*, Jannes *et al.*, Paton *et al.*, Echeverria *et al.*, Fluitt *et al.*, Kinchington *et al.*, and Gilbert *et al.* because each reference teaches a specific region unique to the virus or bacteria. Also, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for success of screening for multiple organisms taught because Jannes et al. and Echeverria et al. teach the simultaneous identification of various pathogens.

It would have been obvious to one of ordinary skill in the art to use at least two probes because there are multiple different amplification products to detect;

furthermore, Jannes *et al.* teach that multiple probes can be used to different strains of bacteria.

The rejection is maintained.

Claims 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jannes et al., Claas et al., Paton et al., Kinchington et al., Saikku et al., Gilbert et al., Fluitt et al., and Echevarria et al. as applied to claims 13-16, 18-24 and 29-34 above, and further in view of Fluitt et al. (WO 95/13396. May, 1995; GenEmbl Accession No: A44457), Jannes et al. (WO 96/00298. January, 1996; GenEmbl Accession No: A47982). Both of these references were provided in the correspondence mailed September 10, 2002.

Applicant has amended the claims to require two probes.

Applicant does not present additional arguments for this rejection but includes it in the arguments for both 103 rejections.

The rejection is maintained for reasons as noted above. Furthermore, the amended claims do not require two different SEQ ID#s but just two probes selected from the group and this list includes probes and the complement of the probes as distinct items on the list. It would be obvious to use a plus and minus sense of a probe to detect pcr products because amplified nucleic acid (DNA) contains a sequence and the complement of the sequence.

The rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23-25, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to require "at least two" probes.

Applicant has not pointed to support for this amendment and the examiner does not see support from a quick review of the specification.

Applicant is requested to point out support.

Allowable Subject Matter

Claims 17, 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

After review of the previous action, it is concluded that the allowable subject matter was indicated as above, i.e.: sets of primer pairs that are used in the claimed

method. None of the claims drawn to individual primers were indicated as allowable. The withdrawn product claims are not the same scope as the product used in the indicated allowable claims.

The rejoinder of claims can occur when the pending are free of rejections and objections and the claims to be rejoined are of the same scope as the allowed claims.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
2/28//07

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600